GE Healthcare

GE Healthcare, Surgery
384 Wright Brothers Drive
Salt Lake City, Utah 84116
U.S.A.

Certified Mail Receipt Requested

URGENT RECALL NOTICE

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVANT SYSTEM(S) OF THESE ISSUES AND HOW TO ADDRESS THEM

November 6, 2009
FMI 15098

To:	**Hospital Administrator**
	Director/Manager of Radiology
Subject:	**Product Safety Issues**
Affected Products:	**GE OEC® 9800**

Our records indicate that your facility has one or more GE OEC 9800 C-arm.

On November 8, 2006 GE Healthcare issued an Urgent Recall Notice after intermittent potential safety issues were identified that may occur with this product based upon feedback from some customers. As a result of the ongoing OEC 9800 product remediation program, additional mitigation steps were found that may reduce the occurrences of some of these issues (Slow Boot, No Boot, Data Loss, Data Mix) until the overall OEC 9800 remediation is completed.

GE Healthcare has discovered that if the OEC 9800 is powered down or shut off while the system is actively working to save or retrieve data to or from the internal hard drive, that there is an increase in the potential safety issues identified, specifically, System No Boot, System Slow to Boot, Patient Data Loss and Patient Data Mix.

Interim Solution:

- Users should exit out to the main menu and wait 1 minute before powering down the 9800.
- Do not remove power or unplug the 9800 until the system has been properly shut down.

It is important to follow all Power Off instructions and labeling in order to minimize the potential for corruption of the system's internal hard drive.

Permanent Solution:

GE Healthcare is actively working on solutions that will resolve these issues. When solutions become available, GE Healthcare Surgery will contact you, and without charge to you, remedy those issues.

If you have any questions or concerns regarding these issues, please do not hesitate to contact the service team for further information at 800-874-7378 option 8. Information is available at this number 24 hours per day, 7 days a week.

Thank You,

Pete McCabe
President
GE Healthcare Surgery

Doug Uelmen
Vice President Quality and Regulatory Affairs
GE Healthcare Surgery